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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,643	01/18/2002	James D. Watson	11000.1008c2	8060

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	5

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,643	WATSON ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-8 are pending and under consideration.

Specification

The disclosure is objected to because of the following informalities:

Page 1, lines 10-12, the status of the applications in the Priority Statement must be updated,

Page 3, line 9, "theorises" should be "theorizes"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing eosinophil accumlation in murine lungs following ovalbumin administration, does not reasonably provide enablement for treatment of asthma in a patient by administration of delipidated and deglycolipidated *M. vaccae* cells (DDMV). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. In addition, an article published in May 2001, coauthored by one of the co-inventors of the instant specification, Paul L.J. Tan, raises questions concerning enablement of the instant claims (Shirtcliffe et al, *American Journal of Respiratory and Critical Care Medicine*, 163(6):1410-1414).

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is a method for the treatment of asthma in a patient comprising administering to said patient a composition comprising delipidated and deglycolipidated *M. vaccae* cells (DDMV), wherein said DDMV comprise $\leq$10% by weight of lipids, or wherein said DDMV comprise $\geq$33% by weight of amino acids.

The instant specification teaches that asthma is a chronic inflammatory disorder of the airways in which many cells play a role, including mast cells and eosinophils and that the inflammation causes symptoms which are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment, and causes an associated increase in airway responsiveness to a variety of stimuli. Cecil's Textbook of Medicine reinforces applicants' definition of asthma as being a multifactorial disease with multiple manifestations, one of which is eosinophilia, and which is treated by multiple regimens (*Cecil Textbook of Medicine,* Beeson et al, eds., W.B. Saunders Co., Philadelphia, 1979, pages 955-959).

The amount of direction or guidance present in the instant specification is insufficient to enable the breadth of the instant claims, i.e., treatment of asthma in a patient by administration of the claimed DDMV compositions.

The only working example, Example 2, in the instant specification utilizes mice immunized intraperitoneally with ovalbumin and challenged 28 days later, intranasally, with ovalbumin. Control mice were administered PBS intranasally. Experimental mice received only one composition of DDMV wherein said DDMV comprised approximately 1.3% w/w of lipids and approximately 51% w/w of amino acids. No other DDMV compositions with varying % lipids or varying % amino acids were administered.

In addition, the May 2001, publication states that with treatment of forty-three patients having "stable moderately severe asthma" there was "no difference between either treatment group and the placebo group for any of the outcome variables." The procedure used was an intradermal injection of 50 μg (0.05 mg) of the presumably same DDMV composition of the instant claims versus injections of phosphate buffered saline (Abstract; Discussion). Thus, the failure of DDMV to treat successfully asthma patients in this publication raises questions about the scope of the instant claims, i.e., the enablement of the claims as broadly as they are claimed.

Therefor, based upon the insufficiency of the instant specification and the questions raised by the May 2001 publication, the quantity of experimentation necessary by one of relative skill in the art to determine what compositions may or may not succeed in treatment of patients with asthma constitute merely an invitation to experiment, without a reasonable expectation of success, with DDMV compositions which vary in % of lipids, % of amino acid, time of administration, or doses.

Conclusion

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R P Swartz

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

March 15, 2004